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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,150	12/26/2001	Luc Desnoyers	P3030R1C9	4456

7590 03/24/2005

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,150

Applicant(s)

DESNOYERS ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30, 32-35 and 38-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 30, 35 and 38-41 is/are rejected.
- 7) ☒ Claim(s) 28, 29 and 32-34 is/are objected to.
- 8) ☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed on 12/13/04 has been entered.
2. The rejections of claims 22-41 under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility is withdrawn due to Applicants' arguments.
3. The rejection of claims 22-27, 30-31 & 35-41 under 35 U.S.C. 112, second paragraph, as being indefinite for what constitutes a transmembrane domain is withdrawn due to the cancellation or amendment of the claims.
4. The rejection of claims 35-37 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of "stringent hybridization conditions" is withdrawn due to the cancellation or amendment of these claims.
5. The rejection of claims 22-25, 31, 35-37 & 38-41 under 35 U.S.C. 102(b) as being anticipated by Adams et al. is withdrawn either due to the cancellation or amendment of these claims to recite distinguishing functional language.

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6. Applicant's arguments filed 12/13/04 have been fully considered but they are not deemed to be persuasive.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Exhibit 1, as related to the information disclosure statement filed 5/02/00, fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The exhibit has been placed in the application file, but the information referred to therein has not been considered for the following reasons: A new PTO 1449 has not been submitted, as required, stating the relevant publication data. In other words, no PTO 1449 stating the author, GenBank accession number, date of submission of the sequence to GenBank (i.e., publication date), etc. has been provided. In contrast to Applicants' assertions that Blast results are publications, Blast results searched on a given date is not equivalent to a publication date for submission of a GenBank sequence, etc. Additionally, in contrast to Applicants' assertions on page 8 of the response, no comparison with the claimed SEQ ID NO: 44 has been provided so that the Examiner can assess whether the Blast

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sequences actually constitute prior art (i.e., a full disclosure of what these sequences actually represent compared to that claimed), and for the reasons previously made of record.

As previously made of record, Applicant is again advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP 609 C(1).

9. Claims 28, 29 & 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 22-27, 30 & 35-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper basis nor conception in context with that contemplated within the instant specification at the time of filing the instant application exists for now defining the extracellular domain as "amino acids 77-310". In contrast, Figure 20 merely discloses a "transmembrane domain" at amino acid residue #s 58-76, in which what portion of the PRO4405 polypeptide that may be "extracellular" is not stated. *In arguendo*, N-myristoylation sites are proposed at 6

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different positions between amino acids 77-310, which therefore, are intracellular because these are the putative sites where the scr protein binds to the cytoplasmic face of the plasma membrane. Alternatively, a N-myristoylation site is proposed to exist in the signal peptide (which is cleaved away) and directly adjacent to/in the transmembrane domain. In other words, it is unknown and not disclosed what amino acid residues are located within the “extracellular domain”, if any such domain even exists. Therefore, redefining the extracellular domain as amino acids 77-310 after-the-fact constitutes new matter.

11. Claims 22-27, 30, 35 & 38-41 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper No: 20040902, and as follows.

In contrast to Applicants’ assertions on pages 11-12 of the response, page 71 of the specification specifically states that “[t]he [encoded] PRO polypeptides described herein *may be isolated from a variety of sources*, such as from human tissue types *or from another source...* [emphasis added]”. In contrast, as previously made of record, the sole single *human* polynucleotide species described is PRO4405 of SEQ ID NO: 44. No written description is provided in the specification for any other species of PRO4405 molecules, in which disclosure of a single “human” polynucleotide sequence does not reasonably constitute “the claimed genus of polynucleotides”.

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Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), “an adequate written description of a DNA [product] requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself”. *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) held that claims directed to mammalian FGFs were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single *human* polynucleotide species of SEQ ID NO: 44 has been described in the instant specification.

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

“One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is”.

and that:

“A description of a genus of cDNAs [products] may be achieved by means of a recitation of a representative number of cDNAs [products], *defined by nucleotide sequence*, failing in the scope of the genus or of a recitation of structural features common to the members of the genus, *which features constitute a substantial portion of the genus* [emphasis added]. This is analogous to enablement of a genus under 112, [first paragraph], by showing the enablement of a representative number of species within the genus. See Angstadt, 537 F.2d at 502-03, 190 USPQ at 218”.

In contrast, an invitation for others to discover a representative number of species with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics has not reasonably been provided within the instant specification.

Thus, Applicant was not reasonably in possession of the “claimed genus of polynucleotides”, and

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for the reasons previously made of record; consistent with that further held by the court in *Vas-Cath Inc. v. Mahurkar* previously made of record. See again MPEP 2163.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
March 21, 2005

ROBERT C. HAYES, Ph.D.
PATENT EXAMINER